

## Pathology: Billing and Modifiers

This section includes information about the billing and reimbursement of pathology services.

**Note:** Only a provider with a *Clinical Laboratory Improvement Amendments* (CLIA) certificate and state license or registration appropriate to the level of tests performed may be reimbursed for clinical laboratory tests or examinations. Additional information and links to websites regarding licensing requirements are provided below.

For complete allergy testing information, see the *Allergy Testing and Desensitization* section in the appropriate Part 2 manual.

### Diagnosis Code Requirement

All claims for clinical laboratory tests or examinations (CPT-4 80000 series codes) require an ICD-9-CM diagnosis code.

Providers may not submit the following nonspecific diagnosis codes when ordering billing for laboratory procedures: V70.0, V70.5 – V70.9, V72.0, V72.11, V72.12, V72.19, V72.60 and V72.9.

The exceptions are:

- CPT-4 codes for HIV testing: 86701, 86702 and 86703 may be billed with any ICD-9-CM diagnosis code.
- CPT-4 codes 82270, 82272, 82274, 82465, 83718, 83719, 83721 and 84478 may be billed with non-specific ICD-9-CM diagnosis codes V70.0 and V70.8.
- CPT-4 codes 86803 and 86804 may be billed with non-specific ICD-9-CM diagnosis codes V70.0, V70.5 or V70.9.

### Billing Method Guidelines

Clinical laboratory tests or examinations (CPT-4 80000 series codes) are billed using different methods. Although the method used depends on the contractual or other type of mutual agreement between the facility and the physician and will apply to both inpatient and outpatient services, the principal determinant will be the provisions of the contract the facility has with the Medi-Cal program. Those facilities that are not under contract to Medi-Cal may make an arrangement with the physician that is mutually agreeable within these policy guidelines.

The Department of Health Care Services (DHCS) has defined the billing options as follows:

Split-Billable

Split-billable services: When billing for both the professional and technical service components, a modifier is neither required nor allowed. When billing for only the professional component, use modifier 26. When billing for only the technical component, use modifier TC.

- Physician Billing – Facility bills for both the technical and professional components using one line without a modifier. The facility reimburses the pathologist/pathology group for the professional component per their mutual agreements.
- Facility Billing – Physician bills for both the professional and technical components using one line without a modifier. The physician subsequently reimburses the facility for the technical component according to their mutual agreements.

Not Split-Billable

Services that are not split-billable: These codes are not separately reimbursable to different providers for a professional or technical component. Only one provider may bill for these codes. These codes must not be submitted with modifier 26, TC or 99.

**Modifiers**

The use of modifiers with the procedure codes directs the claims adjudication system to reimburse the correct percentage for the component billed.

Claims for clinical laboratory tests and examinations (CPT-4 80000 series codes) that are split-billable require one of the following modifiers:

**Note:** Modifier 99 must not be billed in conjunction with modifier 26 and/or modifier TC. The claim will be denied.

<u>Modifier</u>	<u>Description</u>
26	Professional component (Split Billing)
TC	Technical component
QW	CLIA waived tests; certifies that the provider is performing testing for the procedure with the use of a specific test kit from manufacturers identified by the Centers for Medicare & Medicaid Services (CMS). Providers must have a current CLIA Certificate of Waiver number registered with the California Department of Public Health (CDPH) Laboratory Field Services (LFS) and Medi-Cal Provider Enrollment Division (PED) to be reimbursed.

<u>Modifier</u>	<u>Description</u>
90	Used when service is performed by an outside laboratory but billed by another provider. Only specified providers may use this modifier.
99	Used when two or more modifiers are necessary to define the procedure. The multiple modifiers used must be explained in the <i>Remarks</i> field (Box 80)/ <i>Additional Claim Information</i> field (Box 19) of the claim.

**Note:** When billing for both the professional and technical service components, a modifier is neither required nor allowed.

**Billing for Reference  
Clinical Laboratories  
With Modifier 90**

The following providers may also be reimbursed for clinical laboratory tests or examinations with modifier 90:

- A licensed clinical laboratory billing for clinical laboratory tests or examinations referred to and performed by another licensed clinical laboratory.
- Physicians billing for a newborn metabolic screening panel (HCPCS code S3620).

**Professional (Split Billing)  
Component Restrictions**

Emergency room physicians, orthopedic surgeons, trauma specialists, surgeons, internists, family physicians, podiatrists and other treating physicians who routinely review pathology results as an integral part of their reimbursed patient care services are not entitled to an additional reimbursement of a professional component for that review. This service, like other diagnostic data evaluation, is covered by the reimbursement for office visit and treatment.

**Modifier 26**

Providers are not reimbursed for the professional component (modifier 26) of pathology claims billed with an Evaluation & Management (E&M) procedure performed by the same provider on the same date of service.

Providers are not reimbursed for the professional component when billing for both the professional and technical service components when pathology services are billed with an E&M procedure performed by the same provider on the same date of service.

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**Laboratory Codes:  
Split-Billable**

When billing for both the professional and technical service components, a modifier is neither required nor allowed. When billing for only the professional component, use modifier 26. When billing for only the technical component, use modifier TC.

**Note:** Modifier 99 must not be billed in conjunction with modifier 26 and modifier TC. The claim will be denied.

**Laboratory Codes:  
Not Split-Billable**

Although most laboratory codes are split-billable, the following laboratory codes are not split-billable and must not be billed with modifier 26, TC or 99.

<u>CPT-4 Code</u>	<u>Description</u>
80500 – 80502	Consultations (Clinical Pathology)
81007 *	Urinalysis; bacteriuria screen, except by culture or dipstick
81025	Urine pregnancy test, by visual color comparison methods
81050	Volume measurement for timed collection, each
82044 *	Albumin; urine, microalbumin, semiquantitative (eg, reagent strip assay)
82962	Glucose, blood by glucose monitoring device(s) cleared by the FDA specifically for home use
83013	Helicobacter pylori; breath test analysis for urease activity, non-radioactive isotope
83014	<i>Helicobacter pylori</i> ; drug administration
83876	Myeloperoxidase (MPO)
83951	Oncoprotein; des-gamma-carboxy-prothrombin (DCP)
85060	Blood smear, peripheral, interpretation by physician with written report

\* CPT-4 codes 81007 and 82044 may be billed with modifier QW. For more information about modifier QW, refer to “Waived Laboratory Codes” on a following page.

<u>CPT-4 Code</u>	<u>Description</u>
85097	Bone marrow, smear interpretation
85397	Coagulation and fibrinolysis, functional activity, not otherwise specified, each analyte
86077	Blood bank physician services; difficult cross match and/or evaluation of irregular antibody(s), interpretation and written report
86078	investigation of transfusion reaction including suspicion of transmissible disease, interpretation and written report
86079	authorization for deviation from standard blood banking procedures (eg, use of outdated blood, transfusion of Rh incompatible units), with written report
86485 – 86580	Immunology
86930	Frozen blood, each unit; freezing (includes preparation)
86931	thawing
86932	freezing (includes preparation) and thawing
88141	Cytopathology, cervical or vaginal (any reporting system); requiring interpretation by physician
88184	Flow cytometry, cell surface, cytoplasmic, or nuclear marker, technical component only; first marker
88185	each additional marker
88187	Flow cytometry, interpretation; 2 to 8 markers
88188	9 to 15 markers
88189	16 or more markers
88291	Cytogenetics and molecular cytogenetics, interpretation and report
88321	Consultation and report on referred slides prepared elsewhere
88720	Bilirubin, total, transcutaneous
89055	Leukocyte assessment, fecal, qualitative orsemiquantitative

CPT-4 code 87905 may be billed with modifier QW. For more information about modifier QW, refer to “Waived Laboratory Codes.”

**Waived Laboratory Codes**

The following tests are considered to be CLIA-waived when performed with a CLIA-waived test kit. These codes must be billed with modifier QW to signify that the CLIA-waived kit was used. Modifier QW certifies that the test was performed by a laboratory with a current and appropriate CLIA certificate and a California clinical laboratory Certificate of Registration.

**Note:** These procedure codes are not waived tests when billed without modifier QW.

<u>HCPCS Code</u>	<u>Description</u>
G0431	Drug screen, qualitative; multiple drug classes by high complexity test method (e.g., enzyme assay, immunoassay), per patient encounter
G0434	Drug screen, other than chromatographic; any number of drug classes, by CLIA waived test or moderate complexity test, per patient encounter

<u>CPT-4 Code</u>	<u>Description</u>
80047	Basic metabolic panel (calcium, ionized)
80048	Basic metabolic panel (calcium, total)
80051	Electrolyte panel
80053	Comprehensive metabolic panel
80061	Lipid panel
80069	Renal function test
80178	Lithium
81003	Urinalysis; automated without microscopy
81007 *	bacteriuria screen, except by culture or dipstick
82010	Acetone or other ketone bodies, serum; quantitative
82040	Albumin; serum, plasma or whole blood
82043	Albumin; urine, microalbumin, quantitative
82044 *	Albumin; urine, microalbumin, semiquantitative (e.g., reagent strip assay)
82055	Alcohol (ethanol); any specimen except breath
82120	Amines, vaginal fluid, qualitative
82150	Amylase
82247	Bilirubin; total

\* Not split-billable and must not be billed with modifier 26, TC or 99.

<u>CPT-4 Code</u>	<u>Description</u>
82271	Blood, occult, by peroxidase activity (eg, guaiac), qualitative; other sources
82274	Blood, occult, by fecal hemoglobin determination by immunoassay, qualitative, feces, 1-3 simultaneous determinations
82310	Calcium; total
82330	ionized
82374	Carbon dioxide (bicarbonate)
82435	Chloride; blood
82465	Cholesterol, serum or whole blood, total
82523	Collagen cross links, any method
82550	Creatinine kinase (CK), (CPK); total
82565	Creatinine; blood
82570	other source
82679	Estrone
82947	Glucose; quantitative, blood (except reagent strip)
82950	post glucose dose (includes glucose)
82951	tolerance test (GTT), three specimens (includes glucose)
82952	tolerance test, each additional beyond three specimens (list separately in addition to primary code)
82977	Glutamyltransferase, gamma (GGT)
82985	Glycated protein
83001	Gonadotropin; follicle stimulating hormone (FSH)
83002	luteinizing hormone (LH)
83036	Hemoglobin; glycosylated (A1C)
<b><u>83516</u></b>	<b><u>Immunoassay for analyte other than infectious agent antibody or infectious agent antigen; qualitative or semiquantitative, multiple step method</u></b>
83605	Lactate (lactid acid)
83655	Lead
83718	Lipoprotein, direct measurement; high density cholesterol (HDL cholesterol)
83721	LDL cholesterol

<u>CPT-4 Code</u>	<u>Description</u>
83861	Microfluidic analysis utilizing an integrated collection and analysis device, tear osmolarity
83880	Natriuretic peptide
83986	pH, body fluid, except blood
84075	Phosphatase, alkaline
84132	Potassium; serum
84155	Protein, total, except by refractometry; serum, plasma or whole blood
84295	Sodium; serum
84443	Thyroid stimulating hormone (TSH)
84450	Transferase; aspartate amino (AST) (SGOT)
84460	Transferase; alanine amino (ALT) (SGPT)
84478	Triglycerides
84520	Urea nitrogen; quantitative
84550	Uric acid; blood
84703	Gonadotropin, chorionic (hCG); qualitative
85014	Blood count; hematocrit (Hct)
85018	hemoglobin (Hgb)
85576	Platelet, aggregation (in vitro), each agent
85610	Prothrombin time
86294	Immunoassay for tumor antigen, qualitative or semiquantitative (eg, bladder tumor antigen)
86308	Heterophile antibodies; screening
86318	Immunoassay for infectious agent antibody, qualitative or semiquantitative, single step method (eg, reagent strip)
86618	Antibody; Borrelia burgdorferi (Lyme disease)
86701	HIV-1
86703	HIV-1 and HIV-2, single assay
<b><u>86780</u></b>	<b><u>Treponema pallidum</u></b>
86803	Hepatitis C Antibody

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CPT-4 Code	Description
87077	Culture, bacterial; aerobic isolate, additional methods required for definitive identification, each isolate
87449	Infectious agent antigen detection by enzyme immunoassay technique qualitative or semiquantitative; multiple step method, not otherwise specified, each organism
87502	Influenza virus, for multiple types or sub-types, multiplex reverse transcription and amplified probe technique, first 2 types or sub-types
87661	Trichomonas vaginalis, amplified probe technique
87804	Infectious agent antigen detection by immunoassay with direct optical observation; Influenza
87807	respiratory syncytial virus
87808	Trichomonas vaginalis
87809	adenovirus
87880	Infectious agent detection by immunoassay with direct optical observation; Streptococcus, group A
87899	not otherwise specified
87905 *	Infectious agent enzymatic activity other than virus (eg, sialidase activity in vaginal fluid)

\* Not split-billable and must not be billed with modifier 26, TC or 99.

Laboratory procedure codes listed below are considered to be CLIA-waived tests and do not require modifier QW:

<u>CPT-4 Code</u>	<u>Description</u>
81002	Urinalysis, by dip stick or tablet reagent; non-automated, with microscopy
81025 *	Urine pregnancy test, by visual color comparison methods
82270	Blood, occult, by peroxidase activity (eg, guaiac), qualitative; feces, consecutive collected specimens with single determination, for colorectal neoplasm screening
82272	Blood, occult, by peroxidase activity (eg, guaiac), qualitative, feces, 1–3 simultaneous determinations, performed for other than colorectal neoplasm screening
82962 *	Glucose, blood by glucose monitoring device(s) cleared by the FDA specifically for home use
83026	Hemoglobin; by copper sulfate method, non-automated
84830	Ovulation tests, by visual color comparison methods for human luteinizing hormone
85013	Blood count; spun microhematocrit
85651	Sedimentation rate, erythrocyte; non-automated

\* Not split-billable and must not be billed with modifier 26 or TC.

**Clinical Laboratory  
Improvement Amendments  
(CLIA) Certification &  
Billing for Pathology**

All Medi-Cal providers billing for laboratory services must have a current CLIA certificate, and must be enrolled and participate in required proficiency testing to be reimbursed. With the exception of those tests that are excluded from CLIA edits as defined by the Centers for Medicare & Medicaid Services (CMS).

CLIA requires all facilities that perform even one test, including waived tests, on “materials derived from the human body for the purpose of providing information for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of, human beings,” to meet certain federal requirements. If a facility performs tests for these purposes, it is considered a laboratory under CLIA and must apply and obtain a certificate from the CLIA program that corresponds to the complexity of tests performed.

Medi-Cal providers with a CLIA Certificate of Waiver or Provider Performed Microscopy Certificate must obtain a Certificate of California Clinical Laboratory Registration from the California Department of Public Health (CDPH), Laboratory Field Services (LFS). Additional information and instructions may be found at the following website:

[www.cdph.ca.gov/programs/lfs/Documents/F-Registration-Instructions.pdf](http://www.cdph.ca.gov/programs/lfs/Documents/F-Registration-Instructions.pdf)

Medi-Cal providers with a CLIA Certificate of Compliance or Accreditation must obtain a California Clinical Laboratory License from the CDPH, Laboratory Field Services. Additional information and instructions may be found at the following website:

[www.cdph.ca.gov/programs/lfs/Documents/F-Lic-Application-Instructions.pdf](http://www.cdph.ca.gov/programs/lfs/Documents/F-Lic-Application-Instructions.pdf)

All types of Certificates are effective for two years, and include:

#### Certificate of Waiver

- Issued to a laboratory that performs only waived tests as listed in *Code of Federal Regulations*, Title 42, Part 493.15.
- Waived tests are those tests that have been determined to be so simple that if performed incorrectly will pose no risk of harm.
- The laboratory must comply with CLIA registration and certificate requirements and follow the manufacturer’s instructions for test performance.

#### Certificate of Provider Performed Microscopy (PPM) Procedures

- Issued to a laboratory in which a physician, midlevel practitioner or dentist performs specific microscopy procedures during the course of a patient’s visit.
- A limited list of microscopy procedures is included under this certificate type and these are categorized as moderate complexity.

Certificate of Registration

- Issued to laboratory to allow the laboratory to conduct non-waived (moderate and/or high complexity) testing until the laboratory is surveyed (inspected) to determine its compliance with the CLIA regulations.
- Only laboratories applying for a certificate of compliance or a certificate of accreditation will receive a certificate of registration.
- Laboratories must provide CMS with proof of accreditation by an approved accreditation program within 11 months of issuance of the Certificate of Registration.

Certificate of Compliance

- Issued to a laboratory once the State Department of Public Health conducts a survey (inspection) and determines that the laboratory is compliant with all applicable CLIA requirements.
- This type of certificate is issued to a laboratory that performs non-waived (moderate and/or high complexity) testing.

**Note:** The above information can also be found in the *Pathology: An Overview of Enrollment and Proficiency Testing Requirements* section of this manual.

**Procedures Subject to Proficiency Testing**

Laboratory certification (LC) codes CLIA Specialty and Subspecialty list is as follows:

<u>Specialty-Subspecialty</u>	<u>LC Code</u>
Histocompatibility	010
Microbiology – Bacteriology	110
Microbiology – Mycobacteriology	115
Microbiology – Mycology	120
Microbiology – Parasitology	130
Microbiology – Virology	140
Diagnostic Immunology – Syphilis Serology	210
Diagnostic Immunology – General Immunology	220
Chemistry – Routine Chemistry	310
Chemistry – Urinalysis	320
Chemistry – Endocrinology	330
Chemistry – Toxicology	340
Hematology	400
Immunohematology – ABO Group & Rh type	510
Immunohematology – Antibody Detection (transfusion)	520
Immunohematology – Antibody Detection (non-transfusion)	530
Immunohematology – Antibody Identification	540
Immunohematology – Compatibility Testing	550
Pathology – Histopathology	610
Pathology – Oral Pathology	620
Pathology – Cytology	630
Radiobioassay	900

**Criteria for One Certificate for Multiple Sites**

Criteria for one certificate for multiple sites is as follows:

Location

Each location where laboratory tests are performed must file a separate application, unless it meets one of the following exceptions as outlined in CFR, Title 42, Sections 493.35(b), 493.43(b) or 493.55(b):

- Laboratories that are not at a fixed location, for example, laboratories that move from testing site to testing site, such as mobile units providing laboratory testing, health screening fairs, or other temporary testing locations may be covered under the CLIA certificate and address of the designated primary site or home base.
- Not-for-profit or Federal, State, or local government laboratories that engage in limited (not more than a combination of 15 types of moderately complex or waived tests per certificate) public health testing may file a single application.
- Laboratories within a hospital that are located at a contiguous building on the same campus and under common direction may file a single application or multiple applications for CLIA certificate(s) for the laboratory sites within the same physical location or street address.

Home Health Agencies

A parent Home Health Agency (HHA) with multiple branches may apply for one CLIA certificate as long as these sites are under one National Provider Identifier (NPI), for example, parent branch. Subunits by definition operate independently and have a unique provider number; therefore, each subunit must apply for a separate CLIA certificate.

**Note:** The parent or provider location must perform laboratory testing. Because branches cannot operate independently, the parent defines the services provided in the branches and is responsible for the day-to-day operation, supervision, and administration of laboratory testing, including the employment of qualified personnel. (For consistency, the Medicare designated terms parent and branches are used for this policy.)

Hospices

The guidance for HHAs applies to hospices. The Medicare designated term for hospice multiple sites is "multiple locations" rather than branches.

See CMS Update: [www.cms.hhs.gov](http://www.cms.hhs.gov)

**Note:** The above information can also be found in the *Pathology: An Overview of Enrollment and Proficiency Testing Requirements* section of this manual.

**Billing Same Lab  
Procedure More Than  
Once On Same Day**

If the same laboratory procedure is performed more than once on a single date of service to establish a diagnostic “curve,” multiple stains, etc., the procedures must be billed as a single claim line rather than line billing each test. Indicate the specific times the separate test specimens were obtained in the *Remarks* field (Box 80)/*Additional Claim Information* field (Box 19) or on an attached report and enter multiple units in the *Service Units* field (Box 46)/*Days or Units* field (Box 24G) to identify the number of times the test was performed. Refer to the *Pathology Billing Example* sections in this manual for a sample.

**Note:** A number of laboratory procedures are subject to National Correct Coding Initiative (NCCI) edits. To process correctly, claims submitted for multiple lab procedures on the same day may require addition of an NCCI-associated modifier. Information about NCCI-associated modifiers is included in the *Correct Coding Initiative: National* section of this manual.

**Evocative/Suppression  
Testing: Billing Multiples of  
The Same Test**

CPT-4 codes 80400 – 80440 (evocative/suppression panel tests) are not reimbursable by Medi-Cal. Providers may separately bill components of these panels that are Medi-Cal benefits (for example, cortisol or renin). If multiples of the same test were performed, providers must show the number of times each test was performed in the *Service Units* field (Box 46)/*Days or Units* field (Box 24G).

**Electronic Billing of  
Laboratory Services**

Providers billing electronically for laboratory services that require medical justification may enter the medical justification in the electronic filing *Remarks* field. Medical justification statements entered in the electronic filing *Remarks* field must not exceed 1,500 characters. If the statement exceeds the character limit, providers must submit a hard copy with the appropriate medical justification documents accompanying the claim.

Exceptions

Claims and “By Report” attachments for the following CPT-4 codes may not be submitted electronically.

**Note:** Refer to the *Pathology: Microbiology* section in this manual for billing information regarding CPT-4 codes 87900, 87903, 87904 and 87906.

<u>CPT-4 Code</u>	<u>Description</u>
83013	Helicobacter pylori; breath test analysis for urease activity, non-radioactive isotope
87620	Infectious agent detection by nucleic acid (DNA or RNA); papillomavirus, human, direct probe technique
87900	Infectious agent drug susceptibility phenotype prediction using regularly updated genotypic bioinformatics

<u>CPT-4 Code</u>	<u>Description</u>
87901	Infectious agent genotype analysis by nucleic acid (DNA or RNA); HIV 1, reverse transcriptase and protease regions
87906	HIV-1, other region (eg, integrase, fusion)
87903	Infectious agent phenotype analysis by nucleic acid (DNA or RNA) with drug resistance tissue culture analysis, HIV 1; first through 10 drugs tested
87904	each additional drug tested

**Gene Expression Profiling:  
HCPCS Code S3854**

HCPCS Level II laboratory code S3854 (gene expression profiling panel for use in the management of breast cancer treatment) is a once-in-a-lifetime procedure that must be billed with ICD-9-CM diagnosis codes 174.0 – 174.9 (malignant neoplasm of female breast). This code is not split-billable, and must not be billed with modifiers 26 or TC.

This benefit applies exclusively to Oncotype DX. Other tests are not benefits of the program.

Reimbursement for code S3854 also requires providers to document on the claim form or on an attachment that all six of the following criteria of early stage breast cancer have been met:

- The recipient is estrogen receptor (ER) positive.
- The recipient is Lymph Node Negative.
- The recipient has Stage I or II breast cancer.
- The recipient is a candidate for chemotherapy.
- The assay is used within six months of diagnosis.
- The intention to treat or not to treat with adjuvant chemotherapy will be contingent, at least in part, on the test results.

Failure to document that all six of the above criteria have been met will result in the claim being denied.

**Note:** This once-in-a-lifetime benefit may now be billed more than once for the same recipient if the provider can prove, via documentation, that the recipient has a new second primary breast cancer that fits the same necessary criteria as listed above.

**Breast and Ovarian Cancer  
Gene Sequence Analysis:  
CPT-4 Code 81211**

CPT-4 code 81211 (complete BRCA1 and BRCA2 gene sequence analysis for susceptibility to breast and ovarian cancer) is a once-in-a-lifetime procedure and requires a *Treatment Authorization Request (TAR)*.

A TAR for code 81211 requires documentation of one or more of the following numbered criteria.

1. For women without diagnosis of breast or ovarian cancer:
  - Two first-degree relatives with breast cancer, one of whom was diagnosed at age  $\leq 50$ ; OR
  - A combination of three or more first- or second-degree relatives with breast cancer regardless of age at diagnosis; OR
  - A combination of both breast and ovarian cancer among first- and second-degree relatives; OR
  - A first-degree relative with bilateral breast cancer; OR
  - A combination of two or more first- or second-degree relatives with ovarian cancer, regardless of age at diagnosis; OR
  - A first- or second-degree relative with both breast and ovarian cancer at any age; OR
  - History of breast cancer in a male relative; OR
  - For women of Ashkenazi Jewish descent, any first-degree relative (or two second-degree relatives on the same side of the family) with breast or ovarian cancer; OR
2. A family history of breast or ovarian cancer that includes a relative with a known deleterious BRCA mutation; OR

3. Personal history of breast cancer plus one or more of the following:
  - Diagnosed at age  $\leq 45$ ; OR
  - Diagnosed at age  $\leq 50$  with  $\geq 1$  close blood relatives with breast cancer diagnosed at age  $\leq 50$  and/or  $\geq 1$  close blood relatives with epithelial ovarian cancer at any age; OR
  - Two breast primaries when first breast cancer diagnosis occurred at age  $\leq 50$ ; OR
  - Diagnosed at age  $\leq 60$  with a triple negative breast cancer; OR
  - Diagnosed at age  $\leq 50$  with a limited family history; OR
  - Diagnosed at any age, with  $\geq 2$  close blood relatives with breast and/or epithelial ovarian/fallopian tube/primary peritoneal cancer at any age; OR
  - Diagnosed at any age with  $\geq 2$  close blood relatives with pancreatic cancer at any age; OR
  - Close male blood relative with breast cancer; OR
  - For an individual of ethnicity associated with higher mutation frequency (for example, founder populations of Ashkenazi Jewish, Icelandic, Swedish, Hungarian or other) no additional family history may be required; OR
4. Personal history of epithelial ovarian cancer/fallopian tube/primary peritoneal cancer; OR
5. Personal history of male breast cancer; OR
6. Personal history of pancreatic cancer at any age with  $\geq 2$  close blood relatives with breast and/or ovarian and/or pancreatic cancer at any age.

Reference:

1. The NCCN Clinical Practice Guidelines in Oncology Breast Cancer (Version 1.2012). 2012 National Comprehensive Cancer Network, Inc. Available at: [http://www.nccn.org/professionals/physician\\_gls/f\\_guidelines.asp](http://www.nccn.org/professionals/physician_gls/f_guidelines.asp). Accessed June 8, 2012.
2. U.S. Preventive Services Task Force. Genetic risk assessment and BRCA mutation testing for breast and ovarian cancer susceptibility recommendation statement. *Ann Intern Med.* *Journal* 2005.143:355.

Reflex BRCA Analysis:  
CPT-4 Code 81211  
Billed with Modifier QP

Reflex BRCA analysis is a once-in-a-lifetime procedure and requires a *Treatment Authorization Request* (TAR).

A TAR for CPT-4 code 81211 billed with modifier QP requires documentation of the following criteria:

- A negative result in the single mutation (CPT-4 code 81215 or 81217) or three-mutation (code 81212) analysis, and
- One or more criteria listed under code 81211

**Breast and Ovarian Cancer Gene Analysis; Uncommon Duplication/Deletion Variants: CPT-4 Code 81213**

CPT-4 code 81213 (BRCA 1, BRCA 2 [breast cancer 1 and 2] [eg, hereditary breast and ovarian cancer] gene analysis; uncommon duplication/deletion variants) is a once-in-a-lifetime procedure and requires a TAR documenting the following:

- A negative result in the full sequence analysis and common duplication/deletion variants in BRCA (CPT-4 code 81211), and
- One or more criteria listed under CPT-4 code 81211

Reference:

1. The NCCN Clinical Practice Guidelines in Oncology Breast Cancer (Version 1.2012). 2012 National Comprehensive Cancer Network, Inc. Available at: [http://www.nccn.org/professionals/physician\\_gls/f\\_guidelines.asp](http://www.nccn.org/professionals/physician_gls/f_guidelines.asp). Accessed June 8, 2012.
2. Maurizia Dalla Palma, Susan M. Domchek, Jill Stopfer, et al. The relative contribution of point mutations and genomic rearrangements in BRCA1 and BRCA2 in high risk breast cancer families. *Cancer Res.* 2008 September 1; 68(17): 7006–7014. Available at: <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2752710/pdf/nihms60652.pdf>. Accessed October 1, 2012

**Breast and Ovarian Cancer  
Gene Analysis: CPT-4 Codes  
81215 and 81217**

CPT-4 codes 81215 and 81217 (full sequence analysis and known familial variant in individuals with a known BRCA1 or BRCA2 mutation in the family for susceptibility to breast and ovarian cancer) are once-in-a-lifetime procedures and require TARs.

A TAR for codes 81215 and 81217 requires documentation of the following criteria:

- A family history of breast or ovarian cancer that includes a relative with a known deleterious BRCA mutation.

**Breast and Ovarian Cancer  
Three-Mutation Analysis:  
CPT-4 code 81212**

CPT-4 code 81212 (three-mutation BRCA1 and BRCA2 analysis for susceptibility to breast and ovarian cancer in Ashkenazi individuals) is a once-in-a-lifetime procedure and requires a TAR.

A TAR for code 81212 requires documentation of the following criteria:

- An individual is of an ethnicity associated with the Ashkenazi Jewish population.
- No additional family history may be required.

**KRAS Mutation Analysis  
Testing: CPT-4 Code 81275**

CPT-4 code 81275 (KRAS gene analysis, variants in codons 12 and 13) is a once-in-a-lifetime procedure. Claims for this service must be billed in conjunction with ICD-9-CM diagnosis code 153.0 – 153.4, 153.6 – 154.2, 159.0, 230.4 or 235.2.